

**A report from The Economist Intelligence Unit**

# Value-based healthcare in France

A slow adoption of  
cost-effectiveness criteria



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## About this report

*Value-based healthcare in France: A slow adoption of cost-effectiveness criteria* is an Economist Intelligence Unit (EIU) report, commissioned by Gilead Sciences. Value-based healthcare looks at health outcomes of treatment relative to cost. In this paper, The EIU looks at the way in which healthcare innovation is assessed in France, the extent to which value for money is influencing price negotiations with the pharmaceutical industry, and the degree to which national guidelines shape healthcare delivery.

In October 2015 The EIU conducted three interviews with experts on value-based healthcare in France; the insights from these in-depth interviews appear throughout the report. The EIU would like to thank the following individuals (listed alphabetically) for sharing their insight and experience:

- Claude Le Pen, professor of economic sciences, Dauphine University, Paris

- Valérie Paris, senior policy analyst, Organisation for Economic Co-operation and Development (OECD), Paris
- Dominique Polton, adviser to the director-general, French National Health Insurance Fund for Salaried Workers (Caisse nationale de l'assurance maladie des travailleurs salariés—CNAMTS)

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# Introduction

France has one of Europe's most comprehensive and streamlined systems in place for assessing the efficacy of new medicines and health technologies and getting them to patients. Yet when it comes to introducing notions of cost-effectiveness or importing value-based concepts throughout the health system, France lags behind many of its neighbours.

Like most other EU countries, France benefits from a universal healthcare system with generous coverage of cutting-edge drugs and medical devices. However, at a time when national budgets are coming under increasing pressure and health ministries across the continent are often forced to make difficult choices about the treatments they will cover, the notion of cost-benefit analysis represents a comparatively new

approach—and one that has yet to filter down to frontline health provision.

“In France, the level of improvement is a key determinant rather than price” in deciding how innovation is valued, explains Claude Le Pen, professor of economic sciences at Dauphine University in Paris. This represents a kind of value-based approach, he adds, but “without this terminology”.

Meanwhile, a lack of transparency in the way in which final prices for new drugs are negotiated and a lack of consistency in healthcare providers' observance of official prescribing guidelines are making it more complicated to assess the extent to which French health authorities are getting real value for money. ■

## 1

## Chapter One: An in-depth assessment of innovation

<sup>1</sup> Sorenson, C, Drummond, M *et al*, "Ensuring value for money in health care: The role of health technology assessment in the European Union," European Observatory on Health Systems and Policies, World Health Organisation, *Observatory Studies Series*, No. 11, 2008, p. 86.

<sup>2</sup> Chalkidou, K, Tunis, S *et al*, "Comparative effectiveness research and evidence-based health policy: Experience from four countries," *The Milbank Quarterly*, Vol. 87, No. 2, 2009, p. 353.

<sup>3</sup> Garrido, MV, Kristensen, FB *et al*, "Health technology assessment and health policy-making in Europe: Current status, challenges and potential," European Observatory on Health Systems and Policies, *Observatory Studies Series*, No. 14, World Health Organisation, 2008, p. 69.

While France's infrastructure for assessing health technology has been in place for several decades, it has assumed its current form only in the past ten years. Central to this system is a two-tiered process for assessing whether the health benefit provided by a new technology warrants inclusion on national lists (service médical rendu—SMR), and the level of innovation it represents compared with existing standards of care (amélioration du service médical rendu—ASMR).

"In France, patient access to new drugs is highly valued," says Dominique Polton, adviser to the director-general of France's National Health Insurance Fund for Salaried Workers (Caisse nationale de l'assurance maladie des travailleurs salariés—CNAMTS). "It shapes the way our system is organised."

Legislation in 2004 created the National Health Authority (Haute Autorité de Santé—HAS) as France's chief health technology assessment (HTA) body, which determines the safety and extent of medical benefits, offers recommendations on reimbursement conditions for healthcare procedures, provides guidelines to healthcare professionals and the general public, and develops hospital accreditation procedures and requirements.<sup>1</sup>

The HAS is an independent, financially autonomous public body. Its unusual funding

model includes not only government and insurers' subsidies, hospital accreditation fees and fees from medical devices and drug manufacturers, but also an additional contribution—totalling around one-third of its budget—from a share of a government tax on the pharmaceutical industry's promotional expenditures.<sup>2</sup>

The agency includes separate committees for drugs, medical procedures and devices.<sup>3</sup> It assumed responsibility for the Transparency Commission (Commission de la transparence), which was established in 1980, and the Economic and Public Health Evaluation Commission (Commission évaluation économique et de santé publique—CEESP), both of which are responsible for determining whether drugs will be included in the benefits basket, as well as the Commission d'évaluation des produits et prestations (CEEP), which makes similar recommendations about medical devices.

The Transparency Commission includes representatives from the government, health insurance funds, health professionals, patient organisations and the pharmaceutical industry, although the industry has no voting rights.

In the case of the most innovative treatments, the Transparency Commission assesses a product's effectiveness compared with other

available treatments or its relative medical benefits. The ASMR scale includes five different levels—major therapeutic benefit, significant therapeutic benefit, modest therapeutic benefit, minor improvement, and no improvement—with those in the first three categories entitled to a price premium.<sup>4</sup>

The CEESP, which originally acted in an advisory capacity to the HAS, was given broader powers in 2012 to consider the cost benefits of new drugs. Its new guidelines gave it the ability to use the same quality-adjusted life year (QALY) measure employed by England's National Institute for Health and Care Excellence (NICE), although there are few signs that this measure is shaping assessments.<sup>5</sup>

The Ministry of Health determines whether new medicines are included in the reimbursable drugs list, the Liste des spécialités pharmaceutiques remboursables aux assurés sociaux. Drugs for the outpatient sector, if approved, are included in the list, with positive lists defined at the national level and applicable throughout the country in all regional authorities. For the inpatient sector, authorised medicines may go on a list of outpatient medicines for use in hospital care, or one restricted to hospitals only.

Since 1994 French legislation has also provided for temporary authorisations (Autorisations temporaires d'utilisation—ATU), which in exceptional cases permit the use of new medical technologies to make available medical products that meet an unmet need but have not yet been granted marketing authorisation. The provision has been used to treat tens of thousands of patients a year.<sup>6</sup>

The National Union of Health Insurance Funds (Union nationale des caisses d'assurance maladie—UNCAM) determines the level of reimbursement for products on the benefits list, and the Economic Committee for Health Products (Comité économique des produits de santé—CEPS) is in charge of setting prices.

Reimbursable drugs sold through retail pharmacies are subject to administered prices, while hospitals are able to negotiate with manufacturers over the pricing for many of the drugs they use. The exceptions are expensive “blockbuster” drugs charged to the health insurance, drugs that are covered by diagnosis-related group (DRG) fixed tariffs or those that outpatients receive from hospital pharmacies. For these categories, companies are obliged to declare prices to the CEPS. If the CEPS does not approve the declared price, it fixes one after a short negotiation.<sup>7</sup>

While the HAS includes medical outcomes in its assessment process to some degree, the interpretation of this measure can be somewhat fluid. The agency evaluates medicines according to their effectiveness and possible side effects or their medical benefit, seriousness of the condition, the curative, preventive or symptomatic properties of the medicines and the public health impact, although the definition of this criterion remains vague in practice.

A 2012 article on pharmaceutical pricing notes that the French interpretation of public-health benefit looks at the benefit of a new drug for the whole population, not just patients: “It is measured along three dimensions: health outcomes produced at population level (which depends on the number of patients with the disease and the effectiveness of the treatment); the fact that the new product covers an unmet medical need; and its impact on the health system (resources saved or displaced within the health system).”<sup>8</sup> The authors add that the unmet-need criteria make it more likely to favour treatments for orphan diseases. In practice, however, the Transparency Commission spends less time considering issues of displacement or savings of resources, making it more difficult to allow for full recognition of the total value to the health system of a given treatment, the article concludes.<sup>9</sup>

<sup>4</sup> Paris, V and Belloni, A, “Value in Pharmaceutical Pricing”, *OECD Health Working Papers*, No. 63, OECD Publishing, 2013, p. 39.

<sup>5</sup> “Is France Creating Its Own NICE?”, Real End Points. Available at: <http://www.realendpoints.com/is-france-creating-its-own-nice>

<sup>6</sup> Bêlorgy, C, “Temporary Authorisations for Use (ATU)”, Agence Française de Sécurité Sanitaire Des Produits De Santé, June 2001.

<sup>7</sup> “France – Pharmaceuticals”, ISPOR Global Health Care Systems Road Map, International Society for Pharmacoeconomics and Outcomes Research, October 2009. Available at: <http://www.ispor.org/htaroadmaps/france.asp>

<sup>8</sup> Paris and Belloni, *Value in Pharmaceutical Pricing*.

<sup>9</sup> *Ibid.*

## Negotiating prices

The CEPS, which includes representatives from the ministries of health, finance and industry, negotiates drug prices with manufacturers based on HAS advice regarding the medical benefit to be derived, with prices of drugs in categories ASMR I to ASMR III considered to be consistent with those of other European countries. This system is unique, as both the level of co-payment and the price negotiations depend on the added value related to effectiveness.<sup>10</sup>

Reimbursement rates can vary from 35% to 65%, while some 30 long-term illnesses are covered in full. Most French citizens have complementary health insurance covering the balance for drug costs. Medical devices are reimbursed at a rate of 65% to 100%, depending on the SMR assessment. Around half of the drugs available in France are included on the positive list of reimbursable drugs, with the majority falling in the 35% bracket.<sup>11</sup>

But there are variations. In the case of fingolimod, a multiple sclerosis (MS) drug, the medicine was classified at ASMR IV and covered at 65%, although MS patients were generally exempt from cost-sharing for treatment.<sup>12</sup>

Because recommendations for the inclusion of drugs on the positive list in France are made on the grounds of clinical benefits and needs prior to the start of price negotiations, the CEPS is expected to reach an agreement on price to enforce the positive recommendation, giving manufacturers substantial leverage in negotiations. This is particularly true in the area of orphan drugs, where rarity and the lack of alternative treatments are key considerations.<sup>13</sup>

The CEPS can also occasionally use volume-price agreements to obtain additional discounts from companies if the sales volumes used as the basis for price negotiation is exceeded.<sup>14</sup>

The costs of new therapies can be considered for generic alternatives, but are usually not taken

into account when their reimbursement status is determined.<sup>15</sup> Generics are typically subject to price capping, usually at around 40% of the original drug's wholesale price before tax.<sup>16</sup>

There is a maximum statutory price for medicines listed for outpatient care and costly hospital medicines, which is set at the time of listing, with international benchmarking for the most innovative drugs.<sup>17</sup>

"The final price is multi-factoral—the level of AMSR, the price in similar countries, volumes, planned volumes and target populations—but because price was supposed to follow independent medical assessment, there has been a kind of value-based pricing," explains Professor Le Pen.

Although French price-setting authorities compare the price of innovative drugs with those in other European countries—principally Germany, Italy, Spain and the UK—there is no formal mechanism for doing so.<sup>18</sup> Between 2007 and 2011 just 8% of drugs introduced to the French market were subject to external reference pricing.<sup>19</sup>

Meanwhile, legislation from late 2011 allowed for a greater emphasis on both comparative-effectiveness data and cost-effectiveness data. As a result, the HAS increasingly requires companies to produce additional evidence to be used to reassess drugs; the prices of innovative drugs are guaranteed for five years but can be reassessed after this point, leading to occasional changes, and sometime reductions, in reimbursement rates. The Transparency Commission reserves the right to reassess the SMR at any time if there are changes in the therapeutic standard.

The increased role of post-marketing research, as well as the ability of the National Agency for the Safety of Medicines and Healthcare Products (Agence Nationale de Sécurité du Médicament et des Produits de Santé—ANSM) to require safety

<sup>10</sup> Garrido *et al*, *Health Technology Assessment*, p. 67.

<sup>11</sup> Bellanger, M, Cherilova, V and Paris, V, "The 'health benefit basket' in France", *European Journal of Health Economics*, 2005, Vol. 6, pp 24–29.

<sup>12</sup> Paris and Belloni, *Value in Pharmaceutical Pricing*, p. 41.

<sup>13</sup> *Ibid.*, p. 50.

<sup>14</sup> *Ibid.*, p. 38.

<sup>15</sup> Sorensen *et al*, *Ensuring value for money in health care*, p. 93.

<sup>16</sup> Ruggeri, K and Nolte, E, *Pharmaceutical pricing: The use of external reference pricing*, RAND Europe, 2013, p. 38.

<sup>17</sup> Paris and Belloni, *Value in Pharmaceutical Pricing*, p. 21.

<sup>18</sup> Sorensen *et al*, *Ensuring value for money in health care*, p. 94.

<sup>19</sup> Ruggeri and Nolte, *Pharmaceutical pricing*, p. 32.



and efficacy studies post-authorisation, puts a new onus on the industry, which must justify any refusal to comply.

An industry article from 2013 argues that, while the new legislation was clearly driven by the need to determine more accurately how much to pay for added medical benefit, “the lack of clear reference cases will make it difficult to provide an answer”.<sup>20</sup> The article goes on to add that “real-life health economic studies could be requested

in the framework of the renewal of the inclusion of a drug in the formulary after its assessment, but observational economics studies might make it very difficult to generate the evidence due to multiple confounding factors and the sample size requested to provide evidence of a statistically significant difference”.<sup>21</sup> In 2016 the ANSM will require drug companies to produce data from active comparator trials to provide an additional evidence base for decisions.

<sup>20</sup> Rémuzat, C, Toumi, M *et al*, “New Drug Regulations in France: What are the Impacts on Market Access? Part 2 – Impacts for Market Access and Impacts for the Pharmaceutical Industry”, *Journal of Market Access and Health Policy*, Vol. 1 (2013).

<sup>21</sup> *Ibid.*



## 2

## Chapter Two: Integrating concepts of value

In the broader healthcare context, France has experimented with many of the same measures for improving healthcare delivery as its European neighbours. It has introduced financial incentives of €40 (US\$43) per patient to encourage different health professionals to work together in multi-disciplinary teams, including the use of bundled payment systems. It has also introduced DRG payments for more than 56% of inpatient expenditures<sup>22</sup> and has piloted payment-for-performance (P4P) programmes.

Yet the terminology around value and outcomes is relatively new—and frequently problematic, according to Valérie Paris, senior policy analyst at the Organisation for Economic Co-operation and Development (OECD) in Paris. “The HAS assesses the added therapeutic value of new drugs and medical devices, and this is the basis for negotiating prices with the manufacturer, because all prices are regulated,” she says. This presents difficulties, she explains, because while drugs with added therapeutic value are eligible for a price that is equivalent to the “international reference price” and higher than that of comparators, “the pricing committee has no ‘rule’ to help it determine how much it should pay for a given benefit.”

The influence of market prices in the therapeutic classes adds a further level of complication, she

says. “If you tried to compute a ‘price per QALY’, for instance in cancer and in diabetes, you would get very different prices. If you are optimistic, you can say it is because people are willing to pay more for cancer, but you can also think that it is only due to market power in cancer.”

While France has introduced P4P incentives for general practitioners (GPs), some specialists and pharmacists, for the latter this is linked to efficiency rather than outcomes, while GPs and specialists are evaluated according to “good quality process of care” in the area of chronic care. “While value-based pricing has gained traction—in the discourse at least and perhaps only temporarily—for drugs, payment for services is still very much based on ‘resource used’, with a supplement for quality in the best cases,” Ms Paris says, adding that a similar observation applies to most OECD countries.

Given the structure of the French healthcare system and decision-making, cost-effectiveness considerations are also less likely to filter lower down the structure, especially at the patient-doctor level, according to those interviewed for this report.

Professor Le Pen points to a recent medical conference in Chicago, at which US doctors criticised the high cost of oncology drugs. “This

<sup>22</sup> Charlesworth, A, Davies, A, and Dixon, J, “Reforming payment for health care in Europe to achieve better value,” *The Nuffield Trust*, August 2012, pp 6, 10, 25-26.

is hardly the case in France, where it is not part of the clinical decision," he says. "French physicians are used to considering themselves in a medical, not economic position. As every price has been fixed by the state, it is the rule of the state to deal with the economic aspects of healthcare, and it is not their job." Any effort to help to bring healthcare providers into the cost discussion will require medical arguments showing an explicit benefit, or lack thereof, to patients, according to Professor Le Pen.

### Cost-effectiveness measures slow to take root

As we have seen previously, French decisions on healthcare coverage are largely made on the basis of need, effectiveness and safety. In the case of medical devices and pharmaceuticals, these criteria also include cost and the degree of innovation. However, in contrast with most of its larger EU neighbours—with the exception of Italy—cost-effectiveness is not yet a key consideration guiding coverage.<sup>23</sup>

In October 2013 the HAS began to use economic evaluation as part of the reimbursement and pricing process for the most innovative medicines on condition that it would not use the new criteria to save money by restricting access to necessary services, but rather, to use available resources more efficiently and fairly.<sup>24</sup>

It was the UK example, Professor Le Pen observes, that persuaded the French authorities to look at cost-effectiveness, although the French approach does not go as far as it does across the Channel. "It is informational cost-effectiveness, part of the final decision-making. They cannot prevent a drug from reaching the market, but it can be used in pricing," he adds, noting that the UK's NICE has no impact on prices but can make a decision about whether a drug is affordable for the country's National Health Service (NHS). "In France, where the government is the price-maker, there is not an issue of the cost-effectiveness ratio being too high. They do have more power," Professor Le Pen says.

The fact that French citizens pay insurance contributions rather than funding healthcare through general taxation also emboldens patients when it comes to demanding the most cutting-edge treatments, according to Professor Le Pen. "If I pay a premium to an insurance company, I have a right to receive a compensation for my premium. French people have the impression that they personally subsidise the healthcare system and have the right to receive a treatment."

He quotes the example of negotiations in the UK over an oncological drug manufactured by Roche, which failed because the drug was estimated to cost around £160,000 (US\$242,000) per QALY, the measure NICE uses to assess cost-effectiveness. The UK authorities unsuccessfully requested a 60% price cut for the medication, whereas the French authorities requested and obtained a reduction of 45%, which made the drug viable.

Ms Polton notes that cost-effectiveness has been part of the metric used by the HAS for the past two years, but unlike NICE, the HAS does not use it to define a threshold for inclusion in the benefits package. Rather, it is just one more piece of information used in negotiations on price, she adds. "When the effects of drugs are uncertain the HAS may require the collection of data that will be used to reassess the technology."

In practice, however, healthcare providers are not always consistent in their application of HAS recommendations, Ms Polton observes. With new blockbuster drugs for diabetes, for instance, the HAS advises physicians to be conservative in their first line of treatment, using older drugs in combination with insulin initially, but these recommendations are not always followed, she says. "What we see is that prescribers tend to use more expensive drugs outside guidelines."

In 2013 19% of French patients receiving gliptins (used to treat diabetes) were prescribed the drugs outside market authorisation, according

<sup>23</sup> Garrido *et al*, *Health technology assessment*, p. 74.

<sup>24</sup> Chalkidou *et al*, *Comparative effectiveness research*, p. 360.

to Ms Polton, and a further 8% received them for an indication for which the HAS had assessed the drugs to be ineligible for reimbursement.

### Lack of transparency over price

The opaque nature of the price-setting process at the national level and the tendency of hospitals to conduct further negotiations on prices in some cases has given payers some additional bargaining room, but it has also undermined a sense of transparency regarding decision-making about drugs and pricing.

“Each hospital has its own HTA committee. They have some flexibility and can adapt the [national] decisions, choosing one drug among several and negotiating with companies,” Professor Le Pen explains. “Five or ten years ago the market price was the real price, and there was transparency. More and more there is a dual price—the list price and the rebates that are negotiated by hospitals at the local level.”

With local prices, any rebates negotiated are confidential, he adds. Moreover, rebates are often paid as much as six or nine months after a drug has been sold. “How do you make a decision based on cost-effectiveness if you don’t know the real cost?”

Prices of hospital drugs that are part of a DRG are not subject to government intervention but are negotiated directly between the hospital and the industry.

“There is less and less transparency, and this is true for all countries,” Ms Paris says. “Blockbuster drugs [which are not included in DRG tariffs] are likely to be on a list for which prices are regulated, but if hospitals can buy the drugs at a lower price, they will do it.” In practice, Ms Paris adds, prices of hospital drugs can always be negotiated in principle, but this can only work when there is sufficient competition between treatments. The French HTA system allows prices to be set with an initial rebate and then reassessed afterwards, according to Ms Polton.

Meanwhile France, like many of its neighbours, has also used risk-sharing and other performance-based agreements for pharmaceuticals in an effort to reduce uncertainties about costly drugs.<sup>25</sup> In the case of one schizophrenia treatment that was claimed to improve compliance, the medicine was approved on condition that the company monitor real-life compliance and refund part of social-security spending if compliance targets were not met.<sup>26</sup> In 2012 the CEPS disclosed a second performance-based agreement with the manufacturer of a diabetes medicine that claimed to offer better control of glycaemia; the agreement stipulated that if this result was not demonstrated in the observational study, the price would be reduced and the company would pay a rebate to compensate for the price premium it received.<sup>27</sup>

However, these arrangements are complicated to negotiate and are rarer than volume-price agreements. Their contents are confidential, making it difficult to assess how widely or effectively they are used, as those interviewed for this report point out. Moreover, making such contracts work can be challenging.

“We know these contracts exist, but you must agree on a clinical indicator that is simple, and to make it operational is not easy,” Professor Le Pen highlights. “You need to be able to follow all patients, where everyone agrees what is significant from the patient point of view.”

Ms Paris agrees, noting that there is little information about such deals that is publicly available, with the exception of the number of agreements and possibly the total amount of money the CEPS is able to claw back through such agreements in a given year.

France nevertheless has a certain amount of influence thanks to its market position. According to the latest data from the European Federation of Pharmaceutical Industries and Associations (EFPIA), France’s pharmaceutical market had the highest value (at ex-factory

<sup>25</sup> Huber, B and Doyle, J, “Oncology drug development and value-based medicine”, *Quintiles*, January 8th 2015. Available at: <http://www.quintiles.com/library/white-papers/oncology-drug-development-and-valuebased-medicine>

<sup>26</sup> Paris and Belloni, *Value in Pharmaceutical Pricing*, p. 52.

<sup>27</sup> *Ibid.*, p. 54.

prices) among 32 European countries in 2012, accounting for almost 17% of pharmaceutical sales in Europe.<sup>28</sup> Moreover, according to the latest World Bank data, total healthcare spending (public and private) represented nearly 12% of GDP in France in 2013, the second-highest percentage in the EU after the Netherlands and one of the highest in the world.<sup>29</sup>

Meanwhile, recent pricing-policy changes elsewhere in Europe mean that France's international benchmarking system for innovative drugs is struggling to keep up. "I think the French system has not really measured the impact of these changes," Ms Paris believes. "I think now nobody knows who is paying what."

<sup>28</sup> EFPIA, *The Pharmaceutical Industry in Figures*, Key Data, 2014.

<sup>29</sup> World Bank, *Health expenditure, total (% of GDP)*. Available at: <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS/countries>




## Conclusion

France's system for assessing value in healthcare, like those in neighbouring countries, is very much a work in progress. Although it has a well-refined system for assessing new technologies and determining coverage, some of the certainty in the final price to be paid has dissipated as local hospital committees increasingly negotiate the "real" or unit prices paid for treatments, making it difficult to ascertain the actual level of rebate being granted.

Moreover, despite a stated intention over the past two years to include cost-effectiveness measures as part of the assessment and price-

negotiation process, it remains unclear to what extent this criterion is actually being adopted in decision-making.

French policymakers have been skilful at using a strong market position to make the most innovative health products broadly accessible to the population without having to make difficult cost-benefit decisions. Increasing cost pressures and rivalry between individual institutions and European countries trying to negotiate the lowest price for a new treatment could put this system to the test in the future.



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